

Sub D1

4. (Amended) A balloon angioplasty catheter comprising:
an elongated catheter body;
a balloon including an inflatable envelope portion;
a perfusion lumen extending through the balloon, the perfusion lumen [having a distal end and a proximal end; wherein the perfusion lumen distal end has a smaller cross section than the perfusion lumen proximal end] decreasing distally in cross section within the inflatable envelope portion.

Remarks

Applicants have carefully reviewed the office action dated September 23, 1996. Claims 1-12 are pending in the application. Applicants have amended Claims 1 and 4 to more clearly recite the present invention.

Claims 1-3 were rejected under 35 U.S.C. §102(b) as anticipated by U.S. Patent Nos. 5,522,800 (Crocker '800) or 5,338,300 (Cox '300). Crocker '800 discloses a guidewire lumen 42 in Fig. 2 within elongate tubular body 12, which apparently terminates near tapered portion 66 in Fig. 6, requiring any guidewire to pass within central lumen 54 and perfusion segment 37 to reach guidewire exit port 36 in distal introduction segment 35. Column 6, lines 48-52; Fig. 1. The perfusion lumen disclosed is not distinct from the guidewire lumen as it serves as the guidewire lumen. Applicants respectfully submit Crocker '800 does not disclose a separate guidewire lumen and perfusion lumen. Claim 1 as amended recites a perfusion angioplasty catheter having a

guidewire lumen external to, and distinct from, the guidewire lumen. Figures 32 and 34 of the present application illustrate an embodiment having an external guidewire lumen 213, distinct from perfusion lumen 217. Applicants respectfully submit that Crocker '800 does not disclose a guidewire lumen external to, and distinct from, the perfusion lumen.

Cox '300 discloses a perfusion adapter 30 including a hollow member 32 having flow passage 40, to be positioned between the wall of an artery and an inflated balloon 54 using positioning member 34. Column 5, lines 30-40; Figs. 1, 2B and 3. Adapter 30 can be advanced over a guidewire 86. Column 7, lines 23-32; Fig. 4. As illustrated in Fig. 4, flow passage 40 serves as a guidewire lumen. Claim 1 as amended recites a perfusion angioplasty catheter having a guidewire lumen external to, and distinct from, the guidewire lumen. Applicant respectfully submits Cox '300 does not disclose the claimed invention as the disclosed perfusion device is not an angioplasty catheter, does not have a balloon, and has a common lumen for both perfusion and guidewire. Applicants respectfully submit that Cox '300 does not anticipate the invention recited in Claims 1-3.

Having the guidewire lumen external to the perfusion allows for increased blood flow through the perfusion lumen relative to the flow possible if guidewire or guidewire and guidewire tube were included within the perfusion lumen. As neither Crocker '800 nor Cox '300 disclose the claimed invention, applicants respectfully submit that Claims 1-3 are not anticipated.

Claims 4-6 stand rejected under 35 U.S.C. §102(b) as anticipated by Crocker '800 or Cox '300. Applicants respectfully submit that Cox '300 does not disclose a balloon angioplasty catheter having a decreasing cross section perfusion lumen, for the reasons discussed above with respect to Claim 1. Crocker '800 discloses a central lumen 54 which appears to maintain a constant cross section through the balloon, followed distally by a perfusion segment 37. Fig. 6. Claim 4 as amended recites a perfusion angioplasty catheter, including a perfusion lumen decreasing distally in cross section within the balloon inflatable envelope portion.

The present invention enables inserting a deflated balloon head having a small distal cross section into a narrow stenotic region. Inflating the balloon brings the narrower distal portion of the balloon envelope to bear radially upon the stenosis, widening it. This can be followed by deflation, advancement, and inflation, bringing the entire balloon envelope to bear upon the stenosis. Applicants respectfully submit that as Crocker '800 discloses a constant diameter perfusion lumen within the inflatable envelope portion, Crocker '800 does not disclose the invention recited in Claims 4-6.

Claims 10-12 stand rejected under 35 U.S.C. §102(b) as anticipated by either Crocker '800 or Cox '300. Applicants respectfully submit that Cox '300 does not disclose a balloon angioplasty catheter having a perfusion lumen and collapsible guidewire lumen, for the reasons discussed above with respect to

Claim 1. Crocker '800 discloses a guidewire lumen 42 in Fig. 2 within elongate tubular body 12, which apparently terminates near tapered portion 66 in Fig. 6, requiring any guidewire to pass within central lumen 54 and perfusion segment 37 to reach guidewire exit port 36 in distal introduction segment 35.

Claim 10 recites a balloon angioplasty perfusion catheter including a collapsible guide wire lumen within the perfusion lumen. Applicants respectfully submit that Crocker '800 does not disclose a collapsible guidewire lumen within the perfusion lumen. As illustrated by Fig. 37 of the present application, a collapsible guide lumen provides the advantages of a guidewire lumen when guidewire presence is required, and the advantages of increased perfusion flow when guidewire presence is no longer required. As neither Crocker '800 nor Cox '300 disclose the claimed invention, applicants respectfully submit that Claims 10-12 are not anticipated.

Applicants respectfully request reconsideration and reexamination. Applicants submit that Claims 1-12 are now in condition for allowance and issuance of a patent in due course is respectfully requested. If a telephone conference might be of

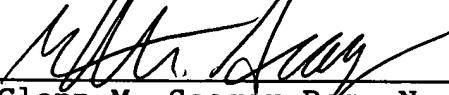
assistance in this matter, please contact the undersigned attorney at (612) 331-1464.

Respectfully submitted,

JAMES E. COX ET AL.

By their Attorney,

Date: Dec. 23, 1991


Glenn M. Seager Reg. No. 36,926
NAWROCKI, ROONEY & SIVERTSON, P.A.
Suite 401, Broadway Place East
3433 Broadway Street Northeast
Minneapolis, Minnesota 55413-3009
Tel: (612) 331-1464